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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,003	01/09/2001	Vijay R. Baichwal	T95-006-2	8531
23379	7590	02/17/2004	EXAMINER	
RICHARD ARON OSMAN SCIENCE AND TECHNOLOGY LAW GROUP 242 AVE VISTA DEL OCEANO SAN CLEMENTE, CA 92672			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/758,003	Applicant(s) BAICHWAL ET AL.	
	Examiner Janet L. Andres	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6 and 10-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,10-27 and 29-34 is/are rejected.
- 7) ☒ Claim(s) 28, 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 28 November 2003 is acknowledged. Claims 1, 3, 5, 6, and 10-35 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

2. The rejection of claims 5 and 6 under 35 U.S.C. 101 is withdrawn in response to Applicant's amendment requiring that the host cell be isolated.

Claim Rejections Maintained

3. The rejection of claims 1, 3, 5-6, 10-27, and 39-34 under 35 U.S.C. 112, first paragraph, as lacking written description is maintained for reasons of record in the office actions of 3 June 2003 and 5 November 2003.

Applicant argues that claim 1 and its dependents require that the encoded polypeptide comprise at least 10 amino acids and that the required common regions is not one amino acid, but one of only ten possible decapeptides. Applicant adds that the encoded polypeptides are limited to those that are immunologically distinguishable from RIP-SER⁵¹⁴. Applicant argues that the polynucleotides of claim 3 and its dependencies are all limited to polynucleotides comprising at least 24 consecutive nucleotides and that the required common region is one of only 22 possible 24-mers. Applicant adds that the polynucleotides are functionally limited to those that hybridize with the RIP-ACA but not RIP-TCT.

Applicant's arguments have been fully considered but have not been found to be persuasive. While claims 1, 5, and 6 are limited to sequences encoding sequences comprising ten possible decapeptides, and claim 3 and 34 to sequences comprising 22 and 14, respectively,

Art Unit: 1646

possible 24-mers, the encoded region that is common among all of the molecules meeting the limitations of claim 1 is in fact one amino acid and the common region among the molecules of claim 3 is the codon for this one amino acid. Two molecules meeting the limitations of the same claim need have no other structural features in common. Claims 10-27 and 29-33 are limited as Applicant indicates, to sequences that encode a sequence comprising a particular decapeptide, or that comprise a particular 24-mer. However, these also vary widely in structure, since they require only ten encoded amino acids or 24 nucleotides. As stated on p. of the office action of 5 November 2003, there are no particular structural or functional characteristics ascribed to these regions. Thus, as stated in the office actions of 5 November 2003 (p. 3) and 3 June 2003 (p. 3), all of the claims encompasses polypeptides that vary widely in length and composition and have no defining common characteristics. Further, as stated in the previous office actions, the limitations of antigenic distinctiveness or of particular hybridization characteristics do not define a genus. The negative limitations do not indicate what the members of the genus have in common, but indicate only that they differ from RIP-ACA/RIP-SER. Antigenicity is further not a defining characteristic; it does not imply any common function or specific structure. Similarly, the ability to hybridize to a particular molecule is not linked to any common structures or functions that would identify members of the genus. In addition, the ability to hybridize is dependent on the conditions used and Applicant has not specified those conditions; thus no particular group of molecules is identified.

4. The rejection of claims 1, 3, 5, 6, 10-27, and 29-34 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate in scope with the claims is maintained for reasons of record in the office actions of 3 June 2003 and 5 November 2003.

Art Unit: 1646

Applicant argues that the claims are drawn to properly, separately disclosed polynucleotides and that the sequence listing rules permit the description of these separately disclosed sequences by reference to a single inclusive SEQ ID NO. Applicant argues that this method of disclosure does not mean that only one sequence is disclosed. Applicant further argues that the specification describes a novel variant and that the claims are all properly restricted to probes or reagents for making them. Applicant further argues that the claims held by the Examiner to be allowable also encompass very different sequences.

Applicant's arguments have been fully considered but have not been found to be persuasive. The sequence rules do permit Applicant to claim sequences comprising fragments of the disclosed sequence; no objection was made based on the sequence rules. However, only one full-length RIP sequence is disclosed and Applicant's claims encompass sequences that are widely divergent from that sequence. The claims are not, as Applicant argues, restricted to probes or reagents for making them. There is no upper limit on the size of the polynucleotides. Fragments limited in size and containing the desired mutation would be enabled for use as probes; however, as written, the claims read on molecules that have not been described so that the skilled artisan could make and use them. As stated in the previous office actions, the specification does not provide guidance for the use of molecules that comprise only a small portion of the disclosed sequence and have no common functional characteristics. The polynucleotides of the claims that have been found to be allowable, in contrast, comprise the entire coding sequence of the polynucleotide and thus contain the essential characteristics of that polynucleotide; it would not require undue experimentation for the skilled artisan to make and use polynucleotides within the scope of the claims that have the same characteristics.

Art Unit: 1646

5. The objection to claims 28 and 35 as depending from rejected claims is maintained for reasons of record in the office actions of 3 June 2003 and 5 November 2003.

The claims from which these claims depend have not been found to be allowable.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (571) 272-0867. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (571) 272-0871. The fax phone number for this group is (703) 872-9306. Communications via internet mail regarding this application, other

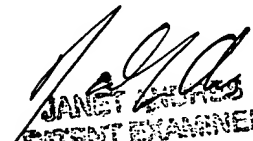
Art Unit: 1646

than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
February 9, 2004



JANET ANDRES
PATENT EXAMINER